

REMARKS

Amendment summary

Claim 1 is amended to recite the presence of Starch 1500 and PCS. This amendment is supported by at least, for example, page 12, lines 10-13 and examples 1 and 2 of the present specification. In addition, as per MPEP § 608.01(v), the use of such trademarks in the claims is proper because the present specification provides a precise and definite definition of Starch 1500 and PCS. In addition, Applicant notes that STARCH 1500 appears in the claims of at least U.S. Patent Nos. 7,393,545; 6,933,380; 6,703,044; 6,399,594; 6,113,920; and 6,350,469. Applicants also submit herewith a brochure for STARCH 1500, which shows that it meets the requirements of the USP/NF, Ph.Eur and JPE compendial monographs. The USP-NF is a combination of two official compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). It contains standards for medicines, drug substances, excipients, and others. The USP-NF provides access to official standards enforceable by the US FDA for drugs and related products manufactured and marketed in the United States. In addition, it serves as a clear, step-by-step guide for the specifications - tests, procedures, and acceptance criteria - required for pharmaceutical manufacturing and quality control. JPE is a world-renowned publication known to people having ordinary skill in the art of formulation technology, and contains a number of monographs including the name of the ingredient or preparation; the definition; packaging, storage and labeling requirements; and the specification consisting of a series of tests, procedures for those tests, and acceptance criteria. The attached brochure of PCS shows that it meets the JPE, USP/NF, and Ph.Eur requirements for a partially pregelatinized starch. In addition, the monograph for PCS, published in 1994 and submitted to the USPTO on December 5, 2008

shows that PCS is known to be a partially pregelatinized starch. Accordingly, use of STARCH 1500 and PCS in the claims is appropriate.

Claims 29-31 are newly added. Support for claims 29 and 30 may be found, for example, at least in Examples 1 and 2 of the present specification. Support for claim 31 may be found, for example, at least in page 13, line 25 to page 14, line 2 of the present specification.

No new matter is added by this Amendment, and entry of this Amendment is respectfully requested.

Response to rejection under 35 U.S.C. § 103 based on Kitazawa in view of Ishihara and further in view of Salpekar

Claims 1, 8, 9, 11, 12, 27, and 28 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kitazawa et al. (U.S. Patent No. 5,387,603) in view of Ishihara et al. (U.S. Patent Application Publication No. 2002/0177593) and in further view of Salpekar et al. (U.S. Patent No. 4,757,090) and Shah (U.S. Patent No. 5,370,878) (hereinafter “Kitazawa,” “Ishihara,” “Salpekar,” and “Shah,” respectively).

Applicants refer the Examiner to Mr. Tsuyoshi Naganuma’s Declaration submitted herewith regarding why the presently claimed invention is not rendered obvious by the cited references. In particular, Kitazawa, Ishihara, Salpekar, and Shar fail to disclose or suggest how to improve the dissolution properties in water for KMD-3213 (which is hardly soluble in water) or how to resolve the filling problems which are caused by the adhesive properties of KMD-3213 during the encapsulating process.

Mr. Naganuma reports on the differences between the physiochemical properties of KMD-3213 and Acetaminophen, including the “notable difference of the dissolution rates

between KMD-3213 and Acetaminophen.” Mr. Naganuma also addresses the Examiner’s positions regarding Ishihara, Salpekar and Shar’s alleged teachings, and states that it is unobvious from the cited references that the presently recited composition would “exhibit immediate dissolution properties and [have] good manufacturing aptitude without causing filling problems during encapsulating process at the same time.” See page 17 of Mr. Naganuma’s Declaration.

Accordingly, Applicants respectfully submit that the presently claimed invention is not rendered obvious by the cited references, and respectfully request the reconsideration and withdrawal of this § 103 rejection.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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